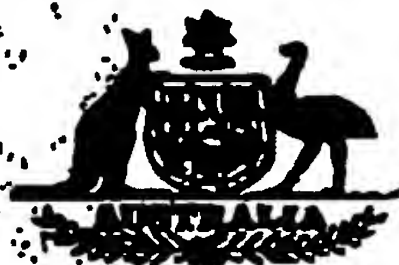


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(12) PATENT SPECIFICATION
ABSTRACT
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(54) DEVICE FOR AT LEAST TEMPORARY OCCLUSION OF BODY CHANNELS
(71) MEDLINE, ARTIEBOLAGET
(72) BRONDIN J.O.
(74) HA
(57) CLAIM

1 A device for at least temporarily occluding channels or hollow spaces in human beings and animals, said device comprising a body, adapted to be inserted into said hollow space, wherein the body consists of a material which swells at least 20% when in contact with body fluid, and which is essentially inert to body fluid and surrounding tissues.

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COMPLETE SPECIFICATION

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Complete Specification for the invention entitled:

**DEVICE FOR AT LEAST TEMPORARY OCCLUSION OF
BODY CHANNELS.**

1.

The following statement is a full description of this invention, including the best method of performing it known to me as

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The present invention relates to a device for temporary or permanent occlusion of channels or hollow spaces in human or animal bodies, particularly oviducts and spermatic ducts.

Human and animal bodies contain a vast number of channels through which fluid and/or other substances or objects can pass or be transported. In certain cases, it is desirable to disrupt such a passage. For contraceptive purposes the spermatic ducts and the oviducts (fallopian tubes) could thus be occluded, whereby the passage of ova and sperms is prevented. In certain vascular diseases, for instance, it may be desirable to stop the flow of blood through certain blood vessels. This is possible both on arterial and vein side of the circulation. The methods hitherto used for this purpose have had disadvantages such as, for instance, that the passage through the channel has been difficult to occlude completely and/or to reopen, when desired. The means used for this purpose have brought problems of fitting: in the case of contraceptive devices such as described in the British Patent Specification No. 1 460 077 there have been problems in providing an occlusion of the current size.

The object of the invention is to provide a device by means of which the disadvantages mentioned above are eliminated which device will make it possible to occlude biological channels in a safe way by adapting of the device to the size of the channel.

Another object of the present invention is to provide a device of the art mentioned which is possible to remove from the biological channel in which it has been

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inserted.

The objects of the invention are obtained by means of a device which is constituted by a body of a material, which, when brought into contact with the body fluid, swells at least 20% and which is essentially inert to the body fluids and to the surrounding tissues.

On the accompanying drawing an embodiment of the invention and its application are shown. In the drawing

Fig. 1 shows a partially sectional view through the oviducts of a woman including the uterus and ovaries and showing devices according to the invention inserted in the oviducts;

Fig. 2 shows in an enlarged scale a transversal sectional view of the device according to the invention and

Fig. 3 is a transversal view of said device.

As mentioned, said device according to the invention is constituted of a body of a material, which, when brought into contact with a body fluid, swells at least 20%. Apart from this swelling, the body is to be essentially inert to the body fluid and to other surrounding tissues. This swelling of the body in contact with body fluid is preferably at least 40%, e.g. at least 80%. It could be varied between 20 and 300% counted as linear expansion. The channels in human beings and animals, which can be occluded by this device are, for example, blood vessels, urethers, spermatic ducts and oviducts.

The geometric form of the body is not critical and can be essentially cylindrical, spherical or eggshaped. However, it has preferably a circular cross-section in the section corresponding to that of the channel to be occluded.

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This cross-section of the body is preferably so much smaller than the cross-section of the channel that the body can conveniently be introduced along the channel.

The device according to the invention is particularly suited for use as a contraceptive device. In this use the body is inserted into the spermatic ducts or the oviducts. The body is in this case preferably attached to a thread in such a way that it can be withdrawn normally without a surgical incision. This thread can be made of an X-ray opaque material enabling localization of the position of the body.

The body itself can also possibly contain substances providing X-ray contrast.

When in contact with the body fluid the material of the body swells at least 20%, preferably at least 40%, e.g. at least 80%, and may even swell as much as 300%. In other respects, the material should be essentially inert and harmless to the body fluid and surrounding tissues and should not be absorbed by the human body. Suitable materials for this purpose are hydrogels. These materials swell by absorbing water from the body fluid. Suitable hydrogels are polymers and copolymers of acrylic type, as e.g. cross-linked polyacrylamide and polymers and copolymers of methacrylic esters having at least one hydroxy radical in the side chain. A preferred monomer is 2-hydroxy-ethyl-methacrylate or the monomethacrylate esters of di- or triethylene glycol or 2,3-dihydroxypropane. As cross-linking agents, polyfunctional acrylates such as diesters or or the same glycols, e.g. ethylene glycol bis-methacrylate, are useful.

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By choosing a copolymer consisting of a hydrophilic monomer and a hydrophobic monomer the expansion factor and water content can be varied within wide limits by varying the ration between the hydrophilic and the hydrophobic monomer. The swelling will increase if the content of the hydrophile monomer is increased.

The body should be essentially elastic and plastic only to a very small extent. In unswollen (non-hydrated) state it may be stiff and/or hard (rigid), but should preferably soften in swelling. The body can contain reinforcing material, e.g. armouring material, and also material making it more X-ray opaque, e.g. salts of barium or bismuth.

In use the body is introduced into the channel in the unswollen state and will thereafter swell, when in contact with the body fluid, so that the body, which can pass through the channel when inserted, will swell and effectively contact the walls of the channel. Through the pressure then exerted by the walls on the body the elastic body will be slightly compressed simultaneously with a possible expansion of the elastic walls of the channel. In this way the body will fill the whole cross-section of the channel and prevent anything from passing through the channel simultaneously with the body being anchored in position. After insertion into an oviduct, the passage of ova to the uterus and spermatozoa, respectively, upwards through the oviduct to the unfertilized ovum will be prevented. After occlusion of a spermatic duct the outward passage of the spermatozoa will be prevented and a good contraceptive action is achieved. If desired, the inserted bodies can be withdrawn by operation or, as is the case when

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inserted in an oviduct, by extraction through the uterus in the case where the body is provided with an attached thread by which said extraction can be performed.

5 A device 1 according to the invention and intended to be inserted in the oviduct of a woman is shown in a longitudinal sectional view in Fig. 2. It is constituted of an elongated, cylindrical (compare Fig. 3) body 2 of the mentioned expandable material with an inner rounded end portion and an outer ball shaped end portion 4. In the
10 body 2 is included a thread made of an X-ray opaque material which terminates on a distance from the end of the inner end portion 3 and which stretches out of the body at the end portion 4 with a free portion 6.

15 In Fig. 1 is shown how the device 1 is inserted in the oviducts 7 of a woman. To the right is shown how the body 1 a short moment after the insertion still keeps its original elongated, narrow shape, which makes it easy to insert in the oviduct 7. To the left is shown how the body 2 after a period in contact with the body tissues has swelled by absorbing the body fluid completely occluding the channel and obtaining a good anchoring to the same. The free
20 portion 6 of the thread 5 extends through the uterus 8 and makes an easy removal of the device possible and also makes it possible to control that the device remains in its intended place.

25 Examples of suitable dimension for the body 2 by the described application are a length of 11 millimetres, the free portion of the thread not included, and a largest diameter of 1,6 millimetres.

30 The body may alternatively be in the form of a drop

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with a diameter of approximately 0.8 millimetre in the unswollen state.

5 The body 2 consists preferably of a hydrophilic monomer as polyvinyl pyrrolidone and a hydrophobic monomer as an acrylate or polyamide by means of copolymerization (graft polymerization) attached to the thread. The swelling and the water absorption power may be altered by changing the proportion of the hydrophilic and the hydrophobic monomer to be polymerized. Three (3) parts of the hydrophilic monomer (vinyl pyrrolidone) and one (1) part of the hydrophobic monomer (polyamide) forms a copolymer having an expansion factor of 1.48 linear (swells 48% in water) with a water content of 66%; five (5) parts of the hydrophilic monomer and one (1) part of the hydrophobic monomer forms a copolymer having a expansion factor of 1.72 with a water content of 78%.

10 The thread 5 is preferably of polyamide fibre, made at least partly X-ray opaque or provided with an X-ray opaque anchoring element.

20 Even though the device according to the invention is described in the form of a contraceptive, it is understood that other applications can be made, for instance, in case of brain damage, such as cerebral haemorrhage, or when treating varicose veins, in which cases a device according to the invention is inserted in the proper vessel to completely obstruct said vessel. In such an application, the hour-glass form is preferred.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1 A device for at least temporarily occluding channels or hollow spaces in human beings and animals, said device comprising a body, adapted to be inserted into said hollow space, wherein the body consists of a material which swells at least 20% when in contact with body fluid, and which is essentially inert to body fluid and surrounding tissues.

2. A device according to claim 1, wherein the material swells at least 40% and preferably at least 80% when in contact with body fluid.

3. A device according to claim 1 or 2, wherein said material consists of a hydrogel.

4. A device according to claim 3, wherein the hydrogel is of acrylic type.

5. A device according to claim 4, wherein said hydrogel is a copolymer of methacrylic esters having at least one hydroxy radical in the side chain with polyfunctional methacrylates.

6. A device according to claim 3, 4 or 5, wherein the hydrogel is a copolymer of at least one hydrophilic monomer and at least one hydrophobic monomer.

7. A device according to claim 5 or 6, wherein the ester moiety of the methacrylic ester is derived from a polyhydric alcohol.

8. A device according to any one of claims 1 to 7, wherein said body contains an X-ray opaque material.

9. A device according to claim 8, wherein an indicator thread is built in or attached to the body, said indicator thread being optionally X-ray opaque.

10. A device according to any one of claims 1 to 9, and intended for the occlusion of an oviduct of a woman, wherein the body has a substantially cylindric, elongated shape with a length of approximately 10 millimetres and a diameter of 1 - 2 millimetres.

11. A method of occluding a channel or hollow space in the body of a human being or an animal which includes the step of inserting therein a device consisting of a material which swells at least 20% when in contact with body fluid.

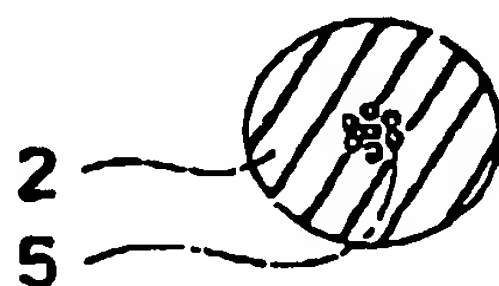
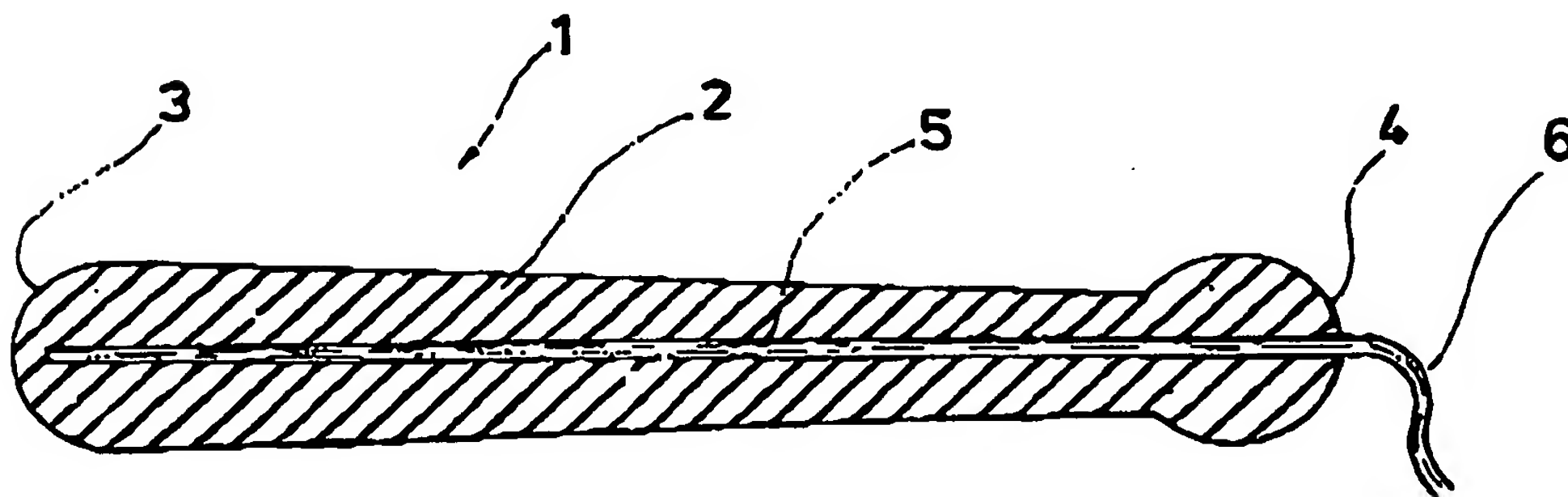
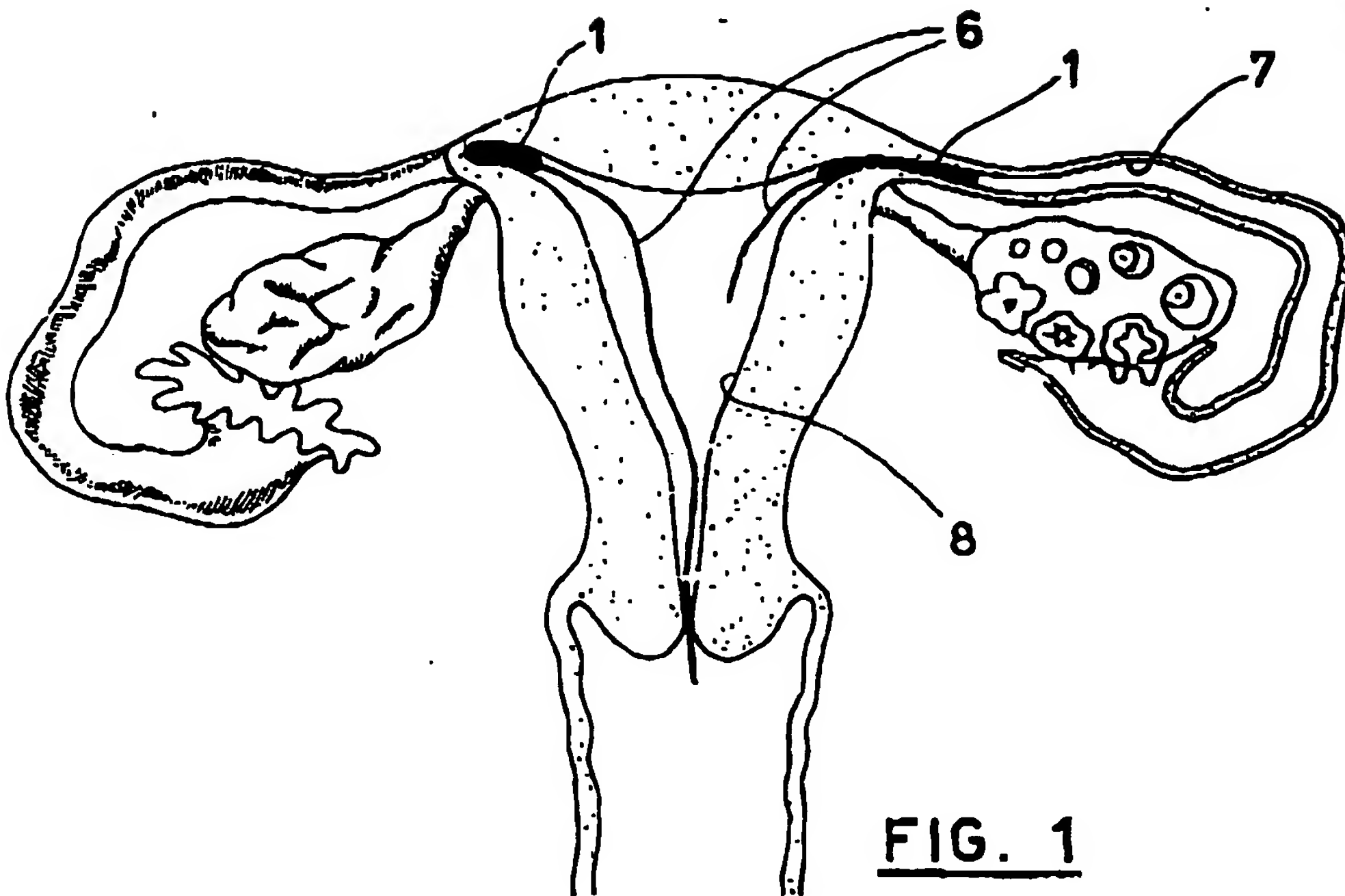
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DATED THIS 17TH DAY OF JANUARY, 1978.

AKTIEBOLAGET MEDLINE
By Its Patent Attorneys

CLEMENT HACK & CO.,
Fellows Institute of Patent
Attorneys of Australia.

32520/78



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